Supreme Court, U.S.
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NO. _____

IN THE
SUPREME COURT OF THE UNITED STATES

TERENCE J. SCALLEN., *Petitioner*
AND,
GALEN D. KNIGHT, *Petitioner*
vs.
THE REGENTS OF THE UNIVERSITY
OF NEW MEXICO, *Respondent.*

On Petition For Writ Of Certiorari To The United States Court Of Appeals For The Federal Circuit

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PETITION FOR WRIT OF CERTIORARI

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and

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ORIGINAL

QUESTIONS PRESENTED

1. Did the Federal Circuit ignore its own precedent and the clear precedent of this Court in failing to recognize that the 1983 University of New Mexico (UNM) Patent Policy misrepresents established law by asserting UNM to be the *initial* owner of employee inventions, without any requirement for inventor assignment, in violation of the Constitution, Article I, § 8, Clause 8?

2. Are inventor assignments demanded by UNM on the basis of this misrepresentation of law invalid?

3. Can UNM, claiming ownership of patents and applications, lawfully make fundamental changes in the content of those applications without authorization from, and over the strenuous objections of, the inventors?

4. Does the consequent publication by UNM of patents in the inventors' names, containing the unauthorized changes referred to in 3) above (changes which the inventors know to be wrong), violate the inventors' right to free speech, more specifically their academic freedom under the First Amendment?

PARTIES TO THE PROCEEDING AND RULE 29.6 STATEMENT

Petitioners are Terence J. Scallen, M.D., Ph.D., *Pro Se*, and Galen D. Knight, Ph.D, *Pro Se*. Petitioners are defendants in the district court (*Regents of the Univ. of N.M. v. Knight*, No. CIV 99-577) and appellants in the Court of Appeals for the Federal Circuit (*Regents of the University of New Mexico v. Knight*, 02-1018, -1019). Respondent is The Regents of the University of New Mexico. Respondent is the plaintiff in the district court and appellee in the Court of Appeals for the Federal Circuit.

Pursuant to Rule 29.6, Petitioners state that both Terence J. Scallen and Galen D. Knight are individuals and represent themselves. There are no corporate interests for either Petitioner.

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TEXT OF CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED

Constitution

1. **Constitution, Article I, § 8, Clause 8:**

   "The Congress shall have power ... to promote progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries:"

2. **Constitution, First Amendment:**

   "Congress shall make no law ... abridging the freedom of speech or of the press;"

Statutes

1. **35 U.S.C. § 111. Application:**

   " (a) In general. (1) Written application. An application for patent shall be made, or authorized to be made, by the inventor ... ."

   "(2) Contents. Such application shall include- a specification as prescribed by section 112 of this title; a drawing as prescribed by section 113 of this title; and an oath by the applicant as prescribed by section 115 of this title."

2. **35 U.S.C. § 115. Oath of Applicant:**

   "The applicant shall make oath that he believes himself to be the original and first inventor of the process, machine, manufacture, or composition of matter or improvement, for which he solicits a patent:"

3. **35 U.S.C. §132. Notice of rejection; reexamination; (a), sentence 2:**

   "No amendment shall introduce new matter into the disclosure of the invention."

Regulations

1. **37 C.F.R. § 1.63(b) and § 1.63(b)(1); Oath or declaration:**

   "(b) In addition to meeting the requirements of paragraph (a), the oath or declaration must state that the person making the oath or declaration:

   (1) Has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration."

2. **37 C.F.R. § 1.67(c), Supplemental oath or declaration:**

   "(c) A supplemental oath or declaration meeting the requirements of § 1.63 must also be filed if the application was altered after the oath or declaration was signed or if the oath or declaration was signed:

   (1) In blank;

   (2) Without review thereof by the person making the oath or declaration; or

   (3) Without review of the specifications, including the claims, as required by § 1.63(b)(1).

PETITION FOR CERTIORARI

Petitioners Terence J. Scallen, M.D., Ph.D., *Pro Se*, and Galen D. Knight, Ph.D., *Pro Se*, respectfully pray that a writ of certiorari issue to review the judgment of the United States Court of Appeals for the Federal Circuit entered in this proceeding on the 28th day of February 2003.

OPINIONS BELOW

The opinion of the Court of Appeals for the Federal Circuit, *Regents of University of New Mexico v. Knight*, (App. A1-27) is reported at 321 F.3d 1111 (Fed. Cir. 2003). The rulings of the district court are unreported (App. A28-49).

JURISDICTION

The judgment of the Court of Appeals for the Federal Circuit was entered on February 28, 2003. Scallen's Petition for Rehearing *En Banc* and Knight's Petition for Panel Rehearing were both timely filed (March 12 and March 14, 2003, respectively). The Court of Appeals denied both petitions for rehearing on April 3, 2003.

The original jurisdiction of the district court was pursuant to 28 U.S.C. §§ 1331, 1338(a) and 2201, and the Patent Laws of the United States, Title 35 of the United States Code; the district court had supplemental jurisdiction pursuant to 28 U.S.C. § 1367.

The jurisdiction of this Court is invoked under 28 U.S.C. § 1254(1).

CONSTITUTIONAL PROVISIONS, STATUTES AND REGULATIONS INVOLVED

Constitution

1. Article I, § 8, Clause 8
2. First Amendment

Statutes

1. 35 U.S.C. § 111 (1994)
2. 35 U.S.C. § 115 (1994)
3. 35 U.S.C. § 132(a), sentence 2 (1994)

Regulations

1. 37 C.F.R. § 1.63(b) and § 1.63(b)(1) (1994)
2. 37 C.F.R. § 1.67(c) (1994)

STATEMENT OF THE CASE

I. Statement of Facts

Scallen was Professor of Biochemistry and Professor of Medicine at the University of New Mexico (UNM). In 1983 when Knight joined Scallen's laboratory as a postdoctoral associate there was a convergence of ideas, findings, and interests from both Knight and Scallen which led to the theoretical postulation of key small regulatory sulfur-containing molecules, related to components of Coenzyme A, which would be capable of regulating multiple cellular metabolic pathways in an *integrated* manner. Experiments were conducted which led to the verification of this hypothesis and which, therefore, led to the vitaletheine modulator and beta-alethine inventions. Regarding beta-alethine, Dr. Paul Mann (hereinafter "Mann") was of great assistance in evaluating these ideas using cultured cells.

By 1986 the inventions had been essentially completed and reduced to practice. On October 31, 1986 an invention disclosure letter was written by the inventors to Dean

Napolitano, Director of the UNM Medical Center. Patent preparation was well under way by June of 1987.

On July 6, 1990 five U.S. patent applications were filed:

1. 07/549,438 Galen D Knight and Terence J. Scallen, *Vitaletheine Modulators and Use in Cell Cultures;*

2. 07/549,105 Galen D. Knight and Terence J. Scallen, *Vitaletheine Modulators in the Prophylaxis and Treatment of Disease;*

3. 07/549,440 Galen D. Knight and Terence J. Scallen, *Therapeutic Use of Vitaletheine Modulators in Neoplasia;*

4. 07/549,104 Galen D. Knight, Paul L. Mann, and Terence J. Scallen, *Beta-alethine Use in Cell Culture and Therapy;*

5. 07/549,103 Galen D. Knight, Paul L. Mann, and Terence J. Scallen, *Beta-alethine As Anti-tumor Agent.*

All five of these original 1990 U.S. patent applications have been abandoned.

Although there is no mention of assignment by inventors in UNM's 1983 Patent Policy (App. A55-58), UNM claimed it was legally entitled to assignment and demanded that Knight and Scallen assign. Because of this claim and these demands Knight and Scallen submitted, and signed assignments (*e.g.*, App. A59-60) for the five 1990 patent applications in 1991.

Five continuation-in part (CIP) applications, containing new experiments (new matter) not present in the 1990 applications, were filed in 1992 in place of each of the 1990 applications and were authorized by Knight and Scallen. Knight and Scallen executed inventor declarations and power of attorney documents for each of the five 1992 CIP

applications. UNM noticed it had no assignment of the 1992 CIP applications in July of 1995, but did not demand same until 1996. Both Knight and Scallen refused.

U.S. Patent 5,370,868 (hereinafter the "'868 patent"), Galen D. Knight and Terence J. Scallen, *Therapeutic Use of Vitaletheine Modulators in Neoplasia*, issued directly from one of the 1992 CIP applications (07/928,725), December 6, 1994, and was authorized by the inventors, Knight and Scallen. This is a patent for the *use* of the vitaletheine modulators in the treatment of neoplasia; it does not claim patent *compound* coverage.

On November 1, 1994 Knight, Scallen, and other collaborating scientists published two articles in *Cancer Research*:

- Knight, G. D., Laubscher, K. H., Fore, M. L., Clark, D. A., and Scallen, T. J. "Vitalethine Modulates Erythropoiesis and Neoplasia", *Cancer Res.* 54, 5623-5635 (1994).
- Knight, G. D., Mann, P. L., Laubscher, K. L., and Scallen, T. J. "The Seemingly Diverse Activities of ß-Alethine", *Cancer Res.* 54, 5636-5642 (1994).

On August 23, 1994 UNM licensed the Knight and Scallen (and Knight, Mann, and Scallen) inventions, patents and applications to Dovetail Technologies, Inc. (Floyd Taub hereinafter "Taub").

In September of 1994 new attorneys (Nixon & Vanderhye), without power of attorney from Knight and Scallen, assumed patent prosecution of the applications.

In 1995-1996 UNM amended various vitaletheine modulator applications without the *prior* knowledge or consent of Knight and Scallen. These amendments changed the compound structures of two of the vitaletheine modulator compounds to structures of different compounds (taurines), i.e., the benzyl derivative (sulfenate-linked benzyl

carbamate dimer) of the vitaletheine compound was changed to carbobenzoxy-beta-alanyl-taurine and vitaletheine V_4 to beta-alanyl-taurine. These taurine compounds were synthesized by Murray and Wallace [agents of Taub (the licensee) and UNM] using synthetic methods different from those taught by Knight and Scallen in the '868 patent. Compound and utility coverage for a third compound, vitalethine, taught in the 1992 CIP applications and in the '868 patent, was deleted by UNM.

These unauthorized amendments gave rise to three unauthorized patents, containing the substituted compounds (taurines):

- U.S. 5,578,313 Galen D. Knight and Terence J. Scallen, *Therapeutic Use of Vitaletheine Modulators in Neoplasia*, issued November 26, 1996;
- U.S. 6,096,536 Galen D. Knight and Terence J. Scallen, *In Vitro Cell Culture in Media Containing Beta-Alanyl-Taurine or Carbobenzoxy-Beta-Alanyl-Taurine*, issued August 1, 2000;
- U.S. 6,323,025 Galen D. Knight and Terence J. Scallen, *In Vitro Cell Culture in Media Containing Beta-Alanyl-Taurine or Carbobenzoxy-Beta-Alanyl-Taurine*, issued November 27, 2001.

In June of 1996, after learning of the changed compound structures contained in a Murray declaration (agent of the licensee), Scallen protested to UNM. *See* App. A80-82. Knight also protested.

On May 20, 1996 Quintana, UNM patent administrator at the time, submitted a document to the Patent Office claiming full right, title, and interest in the vitaletheine modulator applications derived from the 1992 CIPs. However, it is undisputed that UNM did/does not have assignments of the five 1992 CIP applications and their progeny.

On November 26, 1996 U.S. Patent 5,578,313 (hereinafter the '"313 patent") issued. This patent contained the structures of the *changed* compounds in both the specifications and the claims, improperly using the *same* chemical and physical characterization data (data which is *inconsistent* with the chemical nature of the substituted compounds) and also improperly using the *same* biological efficacy data which had been obtained *earlier* by Knight and Scallen using the *original* compounds (as reported previously in the '868 patent).

The inventor declaration contained in the '313 patent file wrapper (App. A75-79) was the *same* inventor declaration contained in the earlier '868 patent file wrapper (App. A68-72), signed by Knight and Scallen on August 10, 1992, swearing to the accuracy of the *1992 CIP applications* containing the original vitaletheine modulator compounds *which resulted in the '868 patent.*

In early 1997 when Knight and Scallen first learned of the issuance of the '313 patent containing these fundamental and unauthorized compound changes, the inventors protested [to Quintana, UNM patent administrator; to Estes, UNM council, App. A83-86; and to the Patent Office] the erroneous changes contained in the '313 patent. In spite of Knight and Scallen's protests UNM took no steps to correct the erroneous changes in the '313 patent. Instead, UNM caused to issue two additional patents (deleting vitalethine and substituting the same two erroneous taurine compounds) as referred to above, *i.e.*, U.S. 6,096,536 and 6,323,025.

UNM has also made unauthorized changes to the claims in the beta-alethine patents, *i.e.*, U.S. 5,643,966, 6,046,241, and 6,245,561.

Since the licensing of the inventions in 1994 Knight and Scallen have been prevented from participating in any way in the patenting process, such as the review and signing of

papers required by the Patent Office in the filing of patents and applications.

II. Proceedings Below

A. Proceedings Before the District Court

On May 21, 1999 UNM filed suit against Knight and Scallen. The complaint (and amended complaint) contained seven counts:

> *Count I* Declaration of Ownership of the Vitaletheine Patents, Patent Applications and Trade Secrets;
>
> *Count II* Declaration of Ownership of the Beta-Alethine Patents, Patent Applications and Trade Secrets;
>
> *Count III* Determination and Correction of Inventorship of Patents;
>
> *Count IV* Breach of Contract;
>
> *Count V* Intentional Interference With Existing Contractual Relations;
>
> *Count VI* Conversion, or in the Alternative, Replevin;
>
> *Count VII* Slander of Title.

Knight and Scallen each filed separate answers and asserted counterclaims.

The district court declared the 1983 UNM Patent Policy the controlling patent policy in this case (March 21, 2000). [1] Scallen then submitted a motion (June 21, 2000) for a declaration by the court that UNM's claim of ownership in the 1983 Patent Policy is invalid. Scallen also submitted a motion (July 3, 2000) for a declaration by the court that the

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[1] Both UNM's complaint and its amended complaint contained a different and more recent " Intellectual Property Policy" which the district court determined was not applicable.

five 1991 assignments by Knight and Scallen are invalid. On January 29, 2001 the district court denied both of these motions, providing no legal analysis.

Scallen asserted that the amendments inserted by UNM, over the objections of the inventors, were/are a violation of his academic freedom (*Doc.* 101, filed March 15, 2000). Knight also raised this issue.

On August 9, 2000 the district court granted summary judgment (Count II) in UNM's favor, declaring UNM the owner of the beta-alethine patents and applications. On January 29, 2001 the district court also granted summary judgment (Count IV, breach of contract) in UNM's favor, as to both the beta-alethine and the vitaletheine patents and applications.

Further, on June 19, 2001 the district court granted UNM's motion to dismiss *with prejudice* Counts V, VI and VII of its amended complaint.

Beginning on June 25, 2001 a four-day bench trial was conducted. The only issue considered was whether or not new matter was introduced when UNM amended certain vitaletheine modulator applications, deleting compound and utility coverage for vitalethine and changing the compound structures of two other vitaletheine modulators taught in U.S. Patent 5,370,868. Three patents, U.S. 5,578,313, 6,096,536 and 6,323,025, have issued incorporating these fundamental changes in compound structures, changes made by UNM over the strenuous objections of the inventors, Knight and Scallen.

On September 10, 2001 the district court submitted its findings of fact and conclusions of law (App. A28-44) and final order (App. A45-49) and declared a) UNM to be the owner of the vitaletheine modulator patents and applications (Count I) and the beta-alethine patents and applications (Count II); b) that no new matter in contravention of 35 U.S.C. § 132 was introduced into the

vitaletheine modulator patents and applications by reason of the amendments made by UNM; c) that Knight and Scallen are the only joint inventors of the vitaletheine modulator patents and applications.

Knight and Scallen filed separate timely appeals to the Federal Circuit.

B. Proceedings Before the Federal Circuit

The Federal Circuit in *Regents of University of New Mexico v. Knight* 321 F.3d 1111 (Fed. Cir. 2003) acknowledges that the inventors, Knight and Scallen, are the initial owners of their inventions (App. A10). However, the court failed to determine whether UNM's 1983 Patent Policy is, in fact, a claim of *initial ownership* of employee inventions (with no requirement for inventor assignment) and is, therefore, a violation of the Constitution (Article I, § 8, Clause 8) and the clear precedent of this Court. If so, the 1983 UNM Patent Policy is an invalid contract.

The Federal Circuit sidestepped the question of the lawfulness of the UNM Patent Policy. Instead, it affirmed the district court judgment on breach of contract (refusal to assign the 1992 CIP applications), based upon the "conduct" of the inventors including the 1991 assignments, as showing "intent" on the part of the inventors that UNM "own" the inventions. *See* App. A12-13. The Federal Circuit then affirmed the district court's judgment on ownership based on the affirmance of the breach of contract judgment (App. A13-18).

The Federal Circuit in its determination of ownership ignored established and settled contract law by basing its decision on the "conduct" of the inventors which was, in fact, improperly controlled by the unlawful misrepresentation of *initial* ownership by UNM in its Patent Policy.

The Federal Circuit affirmed the district court's judgment that no new matter had been added to the vitaletheine modulator patents and applications, based upon the faulty conclusion that the changes in structures did not constitute changes in *compounds* (App. A16-17). This conclusion was unduly influenced by the Federal Circuit's failure to enter the science [App. A17, n 7., "We need not enter the scientific dispute whether the amended structures actually describe the vitaletheine inventions correctly."].

The Federal Circuit did not determine the validity/enforceability of the amended vitaletheine modulator patents containing crucial and critical *content* not supported by inventor oaths or declarations in violation of 35 U.S.C. §§ 111 and 115.

The Federal Circuit also failed to apprehend that the inventors' First Amendment rights (academic freedom) were violated by UNM *causing to be published* certain amended patents *under the inventors' names* which UNM knew the inventors believed to be false.

Scallen filed a petition for rehearing *en banc*, and Knight filed a petition for panel rehearing.

The Federal Circuit denied both petitions on April 3, 2003. *See* App. A50-51.

REASONS FOR GRANTING THE PETITION

Overview

The decision below [*Regents of University of New Mexico v. Knight* 321 F.3d 1111 (Fed. Cir. 2003), App. A1-27] squarely conflicts with the Constitution (Article I, § 8, Clause 8) and with the firmly established precedent of this Court concerning the initial ownership of employee inventions. *See U.S. v. Dubilier Condenser Corp.* 289 U.S. 178, 77 L Ed 1114, 53 S Ct. 554, 85 ALR 1488 (1933). It also conflicts with the Federal Circuit's own precedent, *e.g., Beech Aircraft Corp. v. EDO Corp.,* 990 F.2d 1237, 1248, 26 USPQ2d 1572, 1582

(Fed. Cir. 1993), since the UNM 1983 Patent Policy (App. A55-58) clearly claims *initial* ownership of employee inventions without any requirement for assignment by the inventors.

The Federal Circuit in its decision failed to apply established and settled contract principles concerning the *effect* of this crucial misrepresentation of law on the formation and/or enforceability of contracts, *i.e.*, the Patent Policy and the inventor assignments.

If this decision by the Federal Circuit stands, employers would be permitted to deny inventors the initial ownership of their inventions and to use invalid contracts and statements of supposed legal entitlement in order to improperly obtain assignments.

This case also presents a question of substantial public interest, *i.e.*, the loss of patent coverage for the most potent anti-cancer compounds ever described in the scientific literature, the vitaletheine modulators (*Cancer Res.* article., *supra*, page 4). This occurred because UNM, claiming ownership, deleted from the vitaletheine modulator patents and applications coverage for three strikingly effective and potent biological regulators, two of which are anti-cancer compounds. These changes by UNM were made in spite of the strenuous objections of the inventors (Knight and Scallen) and without inventor authorization. UNM substituted two other compounds (taurines), compounds that have no demonstrated anti-cancer activity whatsoever. Then UNM knowingly caused to be published in the inventors' names patents that the inventors know to be wrong (false).

Clearly, this Court's supervisory powers are required to correct this manifest injustice and to protect the public interest.

I. The Federal Circuit Failed to Determine Whether or Not the 1983 UNM Patent Policy is, in Fact, a Claim of Initial Ownership of Employee Inventions With No Requirement to Assign.

The Federal Circuit's failure to recognize that the 1983 UNM Patent Policy is actually a claim of *initial ownership* of employee inventions casts a cloud of uncertainty over the established precedent of this Court concerning initial ownership by inventors. *See Dubilier, supra.*

The 1983 UNM Patent Policy Claims Initial Ownership of Employee Inventions in the Absence of Any Requirement to Assign.

The 1983 UNM Patent Policy (App. A55-58) was declared by the district court to be the applicable and controlling patent policy in this case.

Section 2 of this Policy states:

> "2. All staff members who make inventions or discoveries (i) in the course of research ... . , such inventions and discoveries belong to the University."

That this claim of ownership by UNM is actually a claim of *initial* ownership is made clear in section 5a of that Policy:

> "In the case of any invention or discovery which *initially* belongs to the University under the provisions of section 2 above, ...". [Emphasis added.]

Further confirmation that UNM claims *initial* ownership is found in a subsequent portion of section 5a:

> "If the President decides that the University will not seek to exploit the invention or discovery for the production of income the University shall promptly assign *its* title thereto to the discoverer or inventor, ..." [Emphasis added.]

This quote provides the only mention of the term "assign" in the entire text of the Patent Policy. This Policy clearly claims *initial* ownership by UNM, with not even a suggestion that the inventions ever belonged to the inventors and, therefore, no suggestion that the inventions must be assigned or transferred to UNM. [2]

"Belong" is defined in *Black's Law Dictionary*: "Belong. Vb. 1. To be the property of a person or thing." *Id.* at 148.

Words and Phrases states:

> "Word 'belong' is not a word of conveyance, but a declaration of *existing* title, and does not evidence an intention to convey or transfer title." *Flynn v. Fike*, 291 Ky. 316, 164 S.W.2d 470, 473 (1942). [Emphasis added.]

Id. at 5, 418.

When coupled with the absence of any language concerning assignment or transfer of rights by the inventors and the use of the phrase "initially belongs to" in section 5a, it is clear that "belongs to" in section 2 of the Patent Policy is a claim of *initial* ownership. [3]

The absence of any transfer language in the UNM Patent Policy stands *in contrast* to two recent cases decided by the Federal Circuit. In *University of West Virginia v. Vanvoorhies*, 278 F.3d 1288, 1292 (Fed. Cir. 2002) the University of West Virginia Patent Policy specifically states and requires the "transfer of rights" from the inventors to the University of West Virginia. *Id.* at 1292. In *Chou v. University of Chicago*, 254 F.3d 1347 (Fed. Cir. 2001) a similar *explicit* requirement,

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[2] It is undisputed that neither Knight nor Scallen were hired to invent.

[3] The Federal Circuit states (App. A11) that the Patent Policy requires "signing of patent applications and associated documents ...". These "associated documents" clearly are documents for obtaining patents. Documents transferring ownership *are not necessary* for obtaining patents, so this statement has no relationship to assignment.

i.e., "shall be assigned", is contained in the University of Chicago Patent Statute. *Id.* at 1357.

No such transfer language is contained in the 1983 UNM Patent Policy. *See* App. A55-58.

The claim of *initial* ownership in UNM's 1983 Patent Policy is contrary to the Constitution and the established precedent of this Court.

Article I, § 8, Clause 8 of the Constitution states:

> "The Congress shall have power ... to promote progress of science and useful arts, by securing for limited times to authors and inventors the exclusive right to their respective writings and discoveries:"

Inventions and patents by law belong to the inventor, unless and until they are assigned to another. *Dubilier, supra* at 187. The UNM Patent Policy claims initial ownership *without even mentioning assignment by the inventor.*

Inventorship provides a *starting point* for determining ownership of patent rights. *Chisum on Patents* (1993) 8, § 22.02, 22-23. [4] In *Beech Aircraft Corp., supra,* the Federal Circuit states:

> "At the heart of any ownership analysis lies the question of who first invented the subject matter at issue, because the patent right *initially* vests in the inventor who may then, barring any restrictions to the contrary, transfer that right to another and so forth." [Emphasis added.]

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[4] Regarding *inventorship* (Count III), the district court determined that Knight and Scallen are the only joint inventors of the vitaletheine modulator inventions, patents, and applications (Count I). *See* App. A49. It is uncontested that Knight, Mann, and Scallen are the only joint inventors of the beta-alethine inventions, patents, and applications (Count II).

Id. at 1248.

Therefore Knight and Scallen (and Knight, Mann, and Scallen), not UNM, are the *initial owners* of the vitaletheine modulator and beta-alethine inventions, patents and applications, respectively, and are under no contractual obligation to assign.

The claim of *initial* ownership by UNM is contrary to law [Constitution (Article I, § 8, Clause 8); *Dubilier;* and *Beech Aircraft Corp.*]. This *misrepresentation* of law is so fundamental and so flawed as to prevent the formation of a contract concerning ownership between the inventors, Knight and Scallen, and UNM.

A misrepresentation can prevent *formation* of a contract. *Restatement Contracts 2d* (1981), 1, § 163, 443. This result, *i.e.*, that a contract concerning ownership (the 1983 Patent Policy) was never formed between UNM and Knight and Scallen, follows "if the misrepresentation relates to the very *nature* of the proposed contract itself and not merely to one of its nonessential terms". *Id.* at 443.

UNM's claim of *initial* ownership is the very *essence and foundation* of the entire Patent Policy. This *misrepresentation* of law either prevented formation of a contract between UNM and the inventors or, in the alternative, rendered it void and unenforceable.

The rules that determine the consequences of a misrepresentation of such a matter of law are the same as those that determine the consequences of a similar misrepresentation of any other fact. *Restatement Contracts 2d* 1, § 170, 463.

The assertions of ownership in the Co-Inventor agreements (App. A11-12) and the assertions of "legal entitlement" contained in the assignments (*e.g.*, App. A59) are based upon this same crucial and fundamental *misrepresentation* of law.

II. The Federal Circuit Failed to Test the Validity of the 1991 Assignments Using Established Principles of Contract Law.

The 1991 Assignments Are Invalid Due to UNM's Misrepresentation of Initial Ownership in the Patent Policy and UNM's Misrepresentation of Legal Entitlement in the Assignments Themselves.

Rather than analyzing the UNM Patent Policy's unlawful claim of initial ownership, the Federal Circuit based its decision regarding breach of contract [5] and ownership *entirely* on the *conduct* of the inventors in submitting to UNM's demands for assignment, without recognizing the effect of the crucial misrepresentation of law in the Patent Policy on the inventors' submission. *See* App. A12-13. This conduct includes the filing of an invention disclosure in 1986, the assigning of the 1990 parent patent applications in 1991, and the signing by the inventors of the Co-Inventor agreements in 1991. The Federal Circuit states that the "conduct" of the inventors, Knight and Scallen, indicates an "intent" that UNM own their inventions. *See* App. A12-13.

Prior to the present litigation Knight and Scallen as scientists, not lawyers, were certainly not experts in patent law and were unable to judge the legitimacy of UNM's claim of *initial* ownership. In 1986 when the inventions were reduced to practice and in 1991 when the assignments of the 1990 applications were demanded, Knight and Scallen were in a *relationship of trust* with UNM, and it was reasonable for the inventors to rely on UMM as the expert.

The *Restatement Contracts 2d*, 1, § 169 states:

> "... , the recipient is not justified in relying on it [assertion] *unless* the recipient (a) stands in such a relation of trust and confidence to the person whose

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[5] The "breach of contract" refers to the refusal of Knight and Scallen to assign the five 1992 CIP applications when they were asked to do so in 1996.

> opinion is asserted that the recipient is reasonable in relying on it or (b) reasonably believes that, as compared with himself, the person whose opinion is asserted has special skill, judgment or objectivity with respect to the subject matter,";

Id. at 459.

Further, § 170 of the *Restatement* states:

> " ... , if the maker of the representation purports to have special expertise in the law which the recipient does not have, reliance on the opinion may be justified (§ 167(b)). If the lawyer states his opinion of law to a layman, the layman is entitled to assume his professional honesty and may justifiably rely on his opinion ...".

Id. at 463.

Knight and Scallen's conduct did *not* reflect an *intent* by the inventors that UNM be the owner of their inventions, but rather reflected their belief *at that time* that they had no choice in the matter and that their "refusal" would be unlawful. Scallen contends that this "conduct" was *improperly controlled/influenced* by the *misrepresentation of law* included in the Patent Policy, i.e., UNM's illicit and unlawful claim of *initial* ownership, and the repeated insistence by UNM officials that assignment was legally required.

A misrepresentation is an assertion that is not in accord with the facts. *Restatement Contracts 2d*, 1, § 159, 426. *Restatement Contracts 2d*, 1, Topic 1, "Misrepresentation" at 425 states:

> " In order to void a contract four things must be shown. *First*, there must have been a misrepresentation (§ 159). *Second*, the misrepresentation must have been either fraudulent or material (§ 162). *Third*, the misrepresentation must have induced the recipient to make the contract (§

167). *Fourth,* the recipient's reliance on the misrepresentation must have been justified." [Emphasis added.]

In addition see *Id.* §§ 169 and 170.

Clearly, all four of these requirements are met in this case.

The assignments (*e.g.,* App. A59-60) begin with the assertion:

> "whereas under its *stated policy* [Patent Policy] Assignee [UNM] is *legally entitled to* ... the entire right, title , and interest ..." [Emphasis added.]

The Co-inventor agreements repeat the same false assertion contained in the Patent Policy, *i.e.,* that UNM is the owner.

This misrepresentation was an *improper inducing cause* for Knight and Scallen to enter into the 1991 assignments and Co-Inventor agreements. As *The Restatement Contracts* 2d, 1, §167 states:

> "A misrepresentation is not a cause of a party's making a contract *unless he relied on the misrepresentation in manifesting his assent.* [Emphasis added.]

Id. at 453.

Therefore the five 1991 assignments are invalid or, in the alternative, void/unenforceable, since UNM claimed in these assignments that it was "*legally entitled*" to them when, *in fact and in law,* it was *not* legally entitled to an assignment since there is no contractual basis for assignment in the Patent Policy. *See* App. A55-58.

III. UNM Amended Certain Vitaletheine Modulator Patents and Applications, Changing the Essential Nature of the Anti-Cancer Compounds Invented by Knight and Scallen, Without Inventor Authorization and Over the Strenuous Objections of the Inventors.

A. The Experimental Scientific Data Prove that the Amendments Added New Matter.

The Federal Circuit misapprehended the *nature* of the amendments to the vitaletheine modulator patents and applications (App. A15-17). The court's statement ("We need not enter the scientific dispute over whether the amended structures actually describe the vitaletheine inventions correctly.") further contributes to this misapprehension. *See* App. A17, n 7. It is true that the Knight and Scallen structures were *changed* by UNM, but it is also true that the *underlying compounds*, described by the *amended* structures, are *fundamentally different* from the *compounds* synthesized by Knight and Scallen and used in all of the inventors' enabling experiments, as reported in *Cancer Research*, as reported in the inventor authorized three 1992 CIP applications, and in U.S. 5,370,868 which was not amended in any way and issued directly from one of the CIPs (07/928,725) in 1994.

The present case is *not* a question of "correction" as assumed by the Federal Circuit in its opinion. *See* App. A16-17. The compound structures, substituted by means of amendments *into* the Knight and Scallen vitaletheine modulator patents and applications by UNM (beta-alanyl-taurine for vitaletheine V_4 and carbobenzoxy-beta-alanyl-taurine for the Knight and Scallen sulfenate-linked benzyl carbamate dimer) are structures of compounds made by the

licensee's agent Murray [6], which are clearly *different compounds* from the Knight and Scallen *compounds*, based upon differing chemical, physical, and biological properties and characteristics. [7]

In other words, the two different sets of structures describe two fundamentally different sets of compounds.

The amendments also deleted from the claims a third compound, vitalethine, included by the inventors in the 1992 CIP applications and taught in the '868 patent. Vitalethine treatment of a very aggressive melanoma in mice was extremely successful: 8 of 10 mice survived when treated with vitalethine (30 fg/kg, administered by injection in saline once every two weeks); 0 of 10 mice survived when treated with saline only. See *Cancer Research* article, *supra*, Table 1, page 5629. *See* App. A87.

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[6] It may seem that the substitution of the compounds synthesized by Murray (taurines) for the Knight and Scallen vitaletheine modulator compounds is inexplicable. It should be noted that Murray and the licensee (Taub) are listed as inventors on patent applications, filed in 1995 three years *after* the filing of the Knight and Scallen 1992 CIP applications. These Murray and Taub applications appear to include *the original Knight and Scallen vitaletheine modulator compounds*, the very compounds *deleted* from the Knight and Scallen patents by UNM and its agents (attorneys paid by Taub). For example, *see* U.S. 6,007,819, Taub, F., Perun, T.J., Murray, C.K., Daughenbaugh, R.J., and Lednicer, D., "Methods of Inducing Immunity Using Low Molecular Weight Immune Stimulants", issued December 28, 1999.

[7] The Federal Circuit states (App. A16): "As the district court found ... Murray and Wallace synthesized the vitaletheine compounds according to Scallen and Knight's descriptions." No documentary evidence, *e.g.*, laboratory notebooks, was presented either in discovery or at trial substantiating this assertion. In fact the record, based upon declarations by Murray and Wallace to the Patent Office, clearly demonstrates that both Murray and Wallace significantly changed the Knight and Scallen procedures taught in U.S. 5,370,868.

The 30 fg/kg dose of vitalethine is 0.000000000000030 grams! This compound and the sulfenate-linked benzyl carbamate dimer of vitaletheine are by far the most potent anti-cancer compounds ever described in the scientific literature.

Comparing the Knight and Scallen vitaletheine modulator compounds with the substituted compounds (taurines), the infrared (IR) spectra are *different*, the mass spectra are *different*, and the elemental analyses are *different*. These are *objective* scientific experimental *measurements* of the compounds themselves, which do not depend upon the structures proposed by the scientists.

For example, the mass spectral data (presented at trial) show that four significant mass ions (above 200 mass units) were observed for the Knight and Scallen sulfenate-linked benzyl carbamate dimer of vitaletheine, i.e., 726 (molecular ion), 547, 378, and 356. Eight mass ions were observed for carbobenzoxy-beta-alanyl-taurine, the compound substituted by UNM, *i.e.*, 755, 474, 396, 394, 392, 331, 225, and 214. *Note that there is not one single ion of the same mass in both spectra.*

Therefore, these are obviously different compounds.

Mass spectrometers and infrared spectrometers are objective and unbiased. Just as different people have different fingerprints, different chemical compounds have different molecular fingerprints.

The failure of UNM to offer experimental evidence that the substituted taurine compounds had/have *any* significant anti-cancer efficacy whatsoever is telling. This is crucial because of the *extraordinary* anti-cancer and immune enhancing activities of the original Knight and Scallen vitaletheine modulator *compounds* (as shown in U.S. 5,370,868 and the *Cancer Research* article, *supra*).

Therefore, the amendments *did* introduce new matter (*new compounds*) and *corrupted the scientific integrity* of Knight and Scallen's inventions. Therefore, UNM added new matter in violation of 35 U.S.C. § 132.

If these amendments present in the '313, '536, and '025 patents are allowed to stand, patent *compound* coverage for the Knight and Scallen enabling vitaletheine modulator compounds (those in U.S. 5,370,868) will be lost. Compound coverage is critical for commercial development. As noted above, the vitaletheine modulators are the most potent anti-cancer compounds ever described in the scientific literature.

This result, *i.e.*, the loss of patent compound coverage and therefore commercial development of the Knight and Scallen vitaletheine modulators, would be *emphatically* against the *public interest*, particularly the interest of the untold numbers of citizens who suffer or will suffer from cancer and numerous immune related diseases, *e.g.*, AIDS, autoimmune disease, and other immunological deficiency states.

A suit to enforce patents and related contracts involves the public interest, as well as the interest of the adverse parties. In *Precision Co., v. Automotive Co.*, 324 U.S. 806, 65 S. Ct. 993, 89 L. Ed. 1381 (1945) this Court states: "A patent by its very nature is affected with a public interest." *Id.* at 816.

Clearly, this Court's supervisory powers are required to correct this manifest injustice and to protect the public interest.

B. Since August of 1994 UNM Has Conducted Patent Prosecution Unlawfully.

Since August of 1994 UNM has not permitted Knight and Scallen to participate in patent prosecution. UNM and its agents have conducted patent prosecution of the Knight and Scallen (and Knight, Mann, and Scallen) patents and applications: 1) without power of attorney from the

inventors, 2) without prior review of patent applications by Knight and Scallen, and 3) without valid declarations or supplemental declarations from the inventors. See "Facts", pages 4-7. *See* Scallen's *First Declaration*, ¶¶ 7-15 (App. A63-64). Thus, UNM has violated 35 U.S.C. § 111 which requires inventor authorization, 35 U.S.C. § 115 which requires valid inventor declarations for issuing patents, and 37 C.F.R. §§ 1.63 and 1.67(c) which require either a new declaration or a supplemental declaration for any changes in the patent application, whether these changes are to specifications or to claims.

The Federal Circuit's statement (App. A13) that the inventors "refused to cooperate" with UNM in patent prosecution is unsupported by the record. The only refusal on the part of the inventors was their refusal in 1996 to assign the 1992 CIP applications and their progeny. In fact the inventors were prevented from cooperating by UNM from August of 1994 on, long before there was any dispute concerning the nature of the compounds. UNM is still preventing cooperation by the inventors to this very day.

The Federal Circuit has failed to apprehend the *manner* by which UNM and its agents deceived the Patent Office into accepting "correction of structures", without revealing to the Patent Office that the amendments actually changed the *compounds*. UNM and its agents falsely represented to the examiner that the inventors agreed with the amendments. This representation was crucial, material, clearly *false*, and UNM knew it. *See* App. A80-86.

Patent, to be valid, had to be granted on application, *supported by oath*, of original and first inventor. *Kennedy v. Hazelton* 128 U.S. 667, 672, 32 L Ed 576, 9 S Ct 202 (1888). This Court states:

> "The patent law makes it essential to the validity of a patent, that it shall be granted on the application, supported by the oath, of the original and first

> inventor, ... whether the patent is issued to him or to his assignee. A patent which is not supported by the oath of the inventor, but applied for by one who is not the inventor, is unauthorized by law, and void, and, whether taken out in the name of the applicant or of any assignee of his, confers no rights as against the public."

Id. at 672.

In *Glaxo Inc. v. Novopharm Ltd.*, 52 F.3d 1043, 1052 (Fed. Cir. 1995) the court states:

> "... the information disclosed in the inventor's patent application must be *that which is actually known to him*. The statute requires that he submit an oath to this effect. See 35 U.S.C. § 115 (1988)." [Emphasis added.]

Id. at 1052.

Further, the *Glaxo* court states;

> "The court finds comfort in the regulations requiring that the inventor sign an oath attesting that he has reviewed the application, 37 C.F.R. §§ 1.41(a), 1.51(a)(2) & § 1.63(b)(1), (2), reasoning that Glaxo must have at least let Crookes [the inventor] review the application before it was filed."

Id. at 1054, note.

The substituted compounds (taurines), introduced by UNM in the amendments, were/are not "known" in the sense that they were not synthesized or used by the inventors, Knight and Scallen in any way. UNM patent administrator Quintana admitted at trial that the inventor declarations included in the *amended* patents and applications by UNM were the *very same* declarations *signed at the time of the CIP applications in 1992* in which the inventors swore (in 1992) to the accuracy of the *compounds*

referred to in the specifications and the claims *of the 1992 CIP applications, prior* to the entry of any of the amendments (1995-1996). Compare the inventor declarations used to support the inventor approved and authorized U.S. 5,370,868 (App. A68-72) with the very same inventor declarations used by UNM to support the *amended* patent, *e.g.*, 5,578,313 (App. A75-79). *See* Scallen's *First Declaration*, ¶¶ 7-15 (App. 63-64).

The inventors never did and never could swear to the accuracy of any of the *amended patents*; the '313 patent issued, November 26, 1996; the '536 patent, August 1, 2000; and the '025 patent, November 27, 2001. The inventors knew, and still know, that the compounds claimed in these *amended* patents are simply wrong. *See* App. A80-86.

Therefore the '313, '536, and '025 patents, and any other patents similarly amended, do not satisfy the requirements of *Kennedy v. Hazelton* and *Glaxo, supra*, violate 35 U.S.C. §§ 111 and 115, and are invalid.

IV. The Consequent Publication by UNM of Patents in Knight and Scallen's Names, Containing Unauthorized Fundamental Changes Which the Inventors Know to be Wrong, Violates Knight and Scallen's Free Speech (Academic Freedom) Under the First Amendment.

The 1940 Statement of Principles on Academic Freedom and Tenure, developed by the American Association of University Professors (AAUP) and the Association of American Colleges and Universities, is the fundamental statement on academic freedom for faculty in higher education. [8] *The 1940 Statement* includes this definition of academic freedom:

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[8] *The 1940 Statement* is included in the UNM *Faculty Handbook*. A New Mexico case [*Garcia v. Middle Rio Grande Conservancy Dist.*, 121 N.M. 528, 918 P.2d 7 (1996)] held that a written personnel policy was a "written contract" and the UNM *Faculty Handbook* is incorporated into Scallen's employment contract (section 8). *See* App. A54. Therefore, in the present

> "Teachers are entitled to full freedom in research and in the *publication* of the results, ..." [Emphasis added.]

This Court has relied on *The 1940 Statement*'s definition of academic freedom. [9] See *Roemer v. Maryland Public Works Bd.*, 426 U.S. 736, 756 (1976); *Tilton v. Richardson*, 403 U.S. 672, 681-82 (1971).

Although this Court has consistently recognized that academic freedom is a First Amendment right, the *scope* of that First Amendment right for university faculty remains unclear. The present case requires determination by this Court to further define that scope.

The amended patents and applications are a violation of Knight and Scallen's First Amendment rights. In *University of California Regents v. Bakke*, 438 U.S. 265, 312 (1978), Justice Powell states:

> "Academic freedom, though not a specifically enumerated constitutional right, long has been viewed as a special concern of the First Amendment."

In *Edwards v. Aguillard*, 482 U.S. 578, 586, 107 S. Ct. 2573 (1987) this Court (quoting the Fifth Circuit Court of Appeals) states:

> "academic freedom embodies the principle that individual instructors are at liberty to teach that which they deem to be appropriate in the exercise of their professional judgment". 765 F.2d at 1257.

Id. at 586, n 6.

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instance, a contract exists between UNM and its faculty members concerning *The 1940 Statement of Principles on Academic Freedom and Tenure.*

[9] *See* Donna R. Euben, "Academic Freedom of Individual Professors and Higher Education Institutions: The Current Legal Landscape" (May, 2002) http://www.aaup.org/Com-a/aeuben.HTM

A patent is a *teaching* and a *publication*, reporting the results and utilities of Knight and Scallen's *research*.

UNM has knowingly caused to be published under Knight and Scallen's names and over Knight and Scallen's protests (*e.g.*, App. A80-86) scientific assertions and content which Knight and Scallen never asserted, nor approved, and which they know to be false. UNM thus corrupted the scientific integrity of these Knight and Scallen *publications* (patents).

Therefore, Knight and Scallen's First Amendment rights have been violated by UNM.

CONCLUSION

For the foregoing reasons, Petitioners respectfully request that their petition for writ of certiorari be granted.

Respectfully submitted,

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